

REMARKS

Claims 1-28 were pending in the application. Claims 1, 2, 6, 20, 21, 22, and 25 have been amended. Upon entry of these amendments, Claims 1-28 will be pending and under active consideration. Claims 1, 6, 20, 21, 25, and 27 are independent. A marked-up version of the claims indicating the changes to the claims is attached hereto as Exhibit B. A copy of all pending claims, as amended, is attached hereto as Exhibit C. The amendments are supported fully by the claims and/or specification as originally filed and, thus, do not represent new subject matter.

The specification is amended at page 4, lines 6-8, to provide clarification as requested by the Examiner and to correct an inadvertent typographical error. A marked-up version of the specification is attached hereto as Exhibit A. No new matter has been added.

Claim 1 has been amended to point out more particularly and claim more distinctly that which Applicants regard as their invention, as requested by the Examiner. The amendment to Claim 1 finds support in the specification, as amended, at page 3, lines 18-25, and page 4, lines 4-8.

Claim 4 has been amended to point out more particularly and claim more distinctly that which Applicants regard as their invention, as requested by the Examiner. The amendment to Claim 4 finds support in the specification, as amended, at page 6, lines 19-24.

Claim 6 has been amended to point out more particularly and claim more distinctly that which Applicants regard as their invention, as requested by the Examiner. The amendment to Claim 6 finds support in the specification, as amended, at page 3, lines 18-25, and page 4, lines 4-8.

Claim 20 has been amended to point out more particularly and claim more distinctly that which Applicants regard as their invention, as requested by the Examiner. The amendment to Claim 20 finds support in the specification, as amended, at page 4, lines 10-26.

Claim 21 has been amended to point out more particularly and claim more distinctly that which Applicants regard as their invention. The amendment to Claim 21 finds support in the specification, as amended, at page 4, lines 4-8.

Claim 22 has been amended to point out more particularly and claim more distinctly that which Applicants regard as their invention, as requested by the Examiner.

Claim 25 has been amended to point out more particularly and claim more distinctly that which Applicants regard as their invention, as requested by the Examiner. The amendment to Claim 25 finds support in the specification, as amended, at page 4, lines 10-26.

Applicants respectfully request entry of the amendments and remarks made herein into the file history of the present invention. Reconsideration and withdrawal of the rejections set forth in the above-identified Office Action are respectfully requested.

I. Rejections Under 35 U.S.C. § 112, First Paragraph

At paragraph 1 of the Office Action, the specification is objected to under 35 U.S.C. § 112, first paragraph, and 37 C.F.R. § 1.71 (a)-(c) as allegedly failing to provide a clear written description of the invention. The Office Action alleges that the term “associated” or “associating” as used in the specification fails to denote the relation of the core particle and the magnetic substance, and that the term “desired magnetic response” as defined in the specification is confusing because the definition is circular. Applicants traverse respectfully.

Applicants submit respectfully that the terms “associated” and “associating,” as used in the specification, for example at page 3, lines 16-26, are generic terms that one skilled in the art would recognize to encompass a number of possible methods of linking, binding, bonding, incorporating, coating, intercalating, adsorbing, absorbing or otherwise pairing one or more magnetic materials or other substances with a core particle or other particle. Examples of such methods are provided in the specification at page 2, lines 3-13, which describes methods of incorporating magnetic material within a core particle and depositing magnetic material onto the surface or into pores of a core particle. Another example is found at page 5, line 27, to page 6, line 4, which describes a method for coupling magnetic nanospheres covalently to the surface of a core particle (microsphere). Thus, Applicants submit respectfully that the terms “associated” and “associating,” as used in the specification, do not fail to denote the relation of the core particle and the magnetic substance.

Further, Applicants submit respectfully that the term “desired magnetic response,” as used in the specification, as amended, is defined clearly, unambiguously, and non-circularly. Without acquiescing in the propriety of the objection, and solely to advance prosecution of the present application, the specification is amended herein to add the following clarifying recitation, as requested by the Examiner, at page 4, lines 6-8: “‘Desired’ implies that the amount and type of magnetic material associated with the core particle are chosen by the skilled artisan to provide a core particle having a magnetic response suitable to achieve the skilled artisan’s preferred end result.” In combination with the definition for magnetic response provided at page 4, lines 4-5, Applicants submit respectfully that the term “desired magnetic response” may be recognized immediately and unambiguously by one skilled in the art to imply a microsphere which, upon exposure to a magnetic field, exhibits an attractive or repulsive force that is suitable to achieve

the skilled artisan's preferred end result, such suitable attractive or repulsive force deriving from the amount and type of magnetic material associated with the core particle as chosen by the skilled artisan to suit his purposes. Page 7, lines 6-13, of the specification provide examples of methods by which a skilled artisan might choose an amount and type of magnetic material to suit his purposes.

On this basis, Applicants submit respectfully that the objections have been overcome, and Applicants request respectfully that the 37 C.F.R. § 1.71 (a)-(c) objections to the specification be withdrawn.

II. Rejections Under 35 U.S.C. § 112, Second Paragraph

At paragraph 2 of the Office Action, Claims 1-28 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to point out particularly and claim distinctly the subject matter regarded as the invention. The Office Action alleges numerous instances of unclear language, each of which is addressed below. Applicants traverse all of the rejections respectfully.

The Office Action alleges that, in Claim 1, the location/position of the substance in relation to the core particle is unclear, that the phrase "associated with the particle" is unclear because it is unclear whether the term "the particle" refers to the particle as a whole or just the core particle, and that it is unclear whether the "desired magnetic response" is the response desired for the substance or for the particle. Applicants respond respectfully that Claim 1, as amended, is clear and unambiguous as to its meaning. Without acquiescing in the propriety of the rejection, and solely to advance prosecution of the present application, Claim 1 is amended herein to make clear that the substance is associated with the core particle (the term "associated"

being defined unambiguously in the specification as described above), that the substance is associated with the core particle and not the particle as a whole, to distinguish between usages of “particle” and “core particle,” and to make clear that the term “desired magnetic response” relates to the particle as a whole. Accordingly, Applicants submit respectfully that the rejection of Claim 1 has been obviated.

The Office Action alleges that, in Claim 2, it is unclear what the term “polymeric magnetic” denotes. The Office Action alleges that there is no substance that is known in the art as a “polymeric magnetic,” and that the specification fails to provide a clear definition of “polymeric magnetic.” The Examiner suggests kindly that the term “polymeric magnetic” be replaced with the exemplary language provided at page 3 or other equivalent description in order to obviate this rejection. Applicants respond respectfully that the term “polymeric magnetic” does not appear in Claim 2 but, rather, it appears in Claim 4, and Applicants will respond as if the Office Action intended the rejection to be directed to Claim 4. Applicants submit respectfully that the term “polymeric magnetic” as applied to the nanosphere of Claim 4, are descriptive terms (adjectives) that are unambiguously defined at page 3, lines 23-25, of the specification as filed and that are used to modify nouns such as “nanosphere,” as used in Claim 4. However, without acquiescing in the propriety of the rejection, and solely to advance prosecution of the present application, Claim 4 is amended herein to replace the term “polymeric magnetic nanosphere” with “nanosphere comprising polymeric material and magnetic material,” in accordance with the Examiner’s suggestion. Accordingly, Applicants submit respectfully that the rejection of Claim 4 has been obviated.

The Office Action alleges further that Claim 4 is confusing. The Office Action alleges that Claim 1, upon which it depends, also recites a desired magnetic response. Thus, it is unclear

whether the “desired” magnetic response in Claim 4 is the same or different from that of Claim 1. Applicants respond that the term “desired magnetic response” does not appear in Claim 4, but, rather, it appears in Claim 5, and Applicants will respond as if the Office Action intended the rejection to be directed to Claim 5. Applicants submit respectfully that Claim 1, as amended, recites “a desired magnetic response” (emphasis added), and that Claim 5 recites “the desired magnetic response” (emphasis added). As Claim 5 depends from Claim 1 (through Claim 4), Applicants submit respectfully that proper interpretation under the rules of claim construction requires that the desired magnetic response of Claim 5 must be the same as the desired magnetic response recited in Claim 1. Accordingly, Applicants submit respectfully that the rejection of Claim 5 is overcome.

Even further, the Office Action alleges that Claim 6 is confusing because it is unclear whether the claim is directed to: (1) a particle and a core particle or (2) a particle comprising a magnetic substance and a core particle. The Office Action alleges further that, in addition, Claim 6 suffers the same deficiency of Claim 1 as discussed above. Without acquiescing in the propriety of the rejection, and solely to advance prosecution of the present application, Claim 6 is amended herein to provide language clarifying the aforementioned issues. Accordingly, Applicants submit respectfully that the rejection of Claim 6 has been obviated.

The Office Action alleges that, in Claim 7, it is unclear whether the reactant is a component of the core particle or of the magnetic substance; and if neither, it is unclear about the location of the reactant in relation to the core and the magnetic substance. Applicants respond respectfully that the language of Claim 7 is not unclear. Applicants submit respectfully that the limitation provided by Claim 7, that the “particle according to Claim 6” further comprise at least one reactant, is directed to the particle as a whole. Applicants submit respectfully that the

limitation need not, and should not, be restricted to either the core particle or magnetic substance as it is applicable to either, or both, or neither (if the particle as a whole further comprises other elements that may contain a reactant). Accordingly, Applicants submit respectfully that the rejection of Claim 7 is overcome.

The Office Action further alleges that, in Claim 15, it is unclear whether the non-magnetic nanospheres are part of the core particle or of the magnetic substance. Applicants submit respectfully that the language of Claim 15 is not unclear. Applicants submit respectfully that the limitation provided by Claim 15, that the “particle according to Claim 14” further comprise non-magnetic nanospheres, is directed to the particle as a whole. As noted above for the rejection of Claim 7, this limitation need not, and should not, be restricted to the core particle or magnetic substance, as the only requirement is that they are part of the particle as a whole. Accordingly, Applicants submit respectfully that the rejection of Claim 15 is overcome.

The Office Action alleges that, in Claim 19, it is unclear whether the fluorescent tag is part of the core or of the magnetic substance; and if neither, it is unclear about the location of the tag in relation to the core and the magnetic substance. Again, Applicants submit respectfully that the limitation provided by Claim 19, that the “particle according to Claim 6” further comprise at least one fluorescent tag, is directed to the particle as a whole, and this limitation need not, and should not, be restricted to the core particle or magnetic substance, as the only requirement is that the fluorescent tag be a part of the particle as a whole. Accordingly, Applicants submit respectfully that the rejection of Claim 19 is overcome.

The Office Action alleges further that Claim 20 is completely confusing. The Office Action alleges that it is unclear what is being claimed and that, in addition, it is unclear what the term “pooled” denotes. Applicants respond respectfully that Claim 20, as amended, is clear and

unambiguous as to its meaning. Without acquiescing in the propriety of the rejection, and solely to advance prosecution of the present application, Claim 20 is amended herein to make clear the subject matter being claimed and the meaning of the term “pooled.” Furthermore, Applicants respectfully direct the Examiner’s attention to page 4, lines 10-26, of the specification as filed which describes and defines pools populations of particles. Accordingly, Applicants submit respectfully that the rejection of Claim 20 is obviated.

The Office Action alleges that, in Claim 21, it is unclear what “associating” process is. As detailed above, Applicants submit respectfully that methods of associating core particles with magnetic substances are recited clearly in the specification as filed. Applicants respectfully direct the Examiner’s attention to page 2, lines 3-13, of the specification as filed which describes methods of incorporating magnetic material within a core particle and depositing magnetic material onto the surface or into pores of a core particle. Further, Applicants respectfully direct the Examiner’s attention to page 5, line 27, to page 6, line 4, which describe a method for coupling magnetic nanospheres covalently to the surface of a core particle (microsphere). Therefore, Applicants submit respectfully that the term “associating” used with reference to a process is clear and unambiguous. Accordingly, Applicants submit respectfully that the rejection of Claim 21 is overcome.

The Office Action alleges that, in Claim 22, it is unclear whether “a core particle” is the same or different from the “particle” that the one magnetic substance was “associated” with. Without acquiescing in the propriety of the rejection, and solely to advance prosecution of the present application, Claim 22 is amended herein to clarify the association of the magnetic substance with the core particle of the particle as a whole. Accordingly, Applicants submit respectfully that the rejection of Claim 22 is obviated.

The Office Action alleges that, in Claim 25, “associating” as a process is unclear as discussed above. In addition, it is unclear how an “amount” can be “associated” with “particles.” As detailed above, Applicants submit respectfully that methods of associating core particles with magnetic substances are indeed recited clearly in the specification as filed. In particular, Applicants respectfully direct the Examiner’s attention to page 2, lines 3-13, of the specification as filed which describes methods of incorporating magnetic material within a core particle and depositing magnetic material onto the surface or into pores of a core particle. Further, Applicants respectfully direct the Examiner’s attention to page 5, line 27, to page 6, line 4, which describes a method for coupling magnetic nanospheres covalently to the surface of a core particle (microsphere). Therefore, Applicants submit respectfully that the term “associating” used with reference to a process is clear and unambiguous. However, without acquiescing in the propriety of the rejection, and solely to advance prosecution of the present application, Claim 25 is amended herein to provide additional clarifying language. Accordingly, Applicants submit respectfully that the rejection of Claim 25 is overcome.

The Office Action alleges further that, in Claim 27, it is unclear whether the “desired magnetic response” of each population is the response “desired” for that particular population or for the pooled set of the populations. Applicants submit respectfully that the language of Claim 27 is not unclear. Applicants submit respectfully that the recitation “combining a population of particles having a desired magnetic response with at least one other population of particles having a different desired magnetic response” is clear and unambiguous with regard to the fact that “having a desired magnetic response” is directed clearly to “a population,” and “having a *different* desired magnetic response” (emphasis added) is directed clearly to “at least one *other*

population of particles” (emphasis added). Accordingly, Applicants submit respectfully that the rejection of Claim 27 is overcome.

The Office Action alleges that, in Claim 27, the term “associated” is unclear to define the relation between the core particles and the magnetic substance. Applicants respond respectfully that the term “associated” does not appear in Claim 27 but, rather, it appears in Claim 28, and Applicants will respond as if the Office Action intended the rejection to be directed to Claim 28. Applicants submit respectfully that, in light of the amendments and remarks already made above, the term “associated” is not unclear to define the relation between the core particles and the magnetic substance. As noted above, examples of methods of associating magnetic substances with core particles are provided in the specification at page 2, lines 3-13, which describes methods of incorporating magnetic material within a core particle and depositing magnetic material onto the surface or into pores of a core particle, and at page 5, line 27, to page 6, line 4, which describes a method for coupling magnetic nanospheres covalently to the surface of a core particle (microsphere). Thus, Applicants submit respectfully that the term “associated” as used in Claim 28, does not fail to denote the relation of the core particle and the magnetic substance. Accordingly, Applicants submit respectfully that the rejection of Claim 27 is overcome.

Finally, the Office Action alleges that other claims are deemed indefinite in view of their dependency on Claims 1, 6, 21, 25 or 26. Applicants submit respectfully that, without acquiescing in the propriety of the rejections of Claims 1, 6, 21, 25 and 26, in light of the amendments and remarks made herein, Claims 1, 6, 21, 25 and 26 are rendered clear and unambiguous and, therefore, any claims depending from those claims are not rendered indefinite in view of their dependency.

On this basis, Applicants suggest respectfully that the rejections of Claims 1-28 under 35

U.S.C. § 112, second paragraph, have been traversed or obviated, and Applicants request respectfully that the 35 U.S.C. § 112, second paragraph, rejections of Claims 1-28 be withdrawn.

CONCLUSION

Applicants submit that the application is in condition for allowance. Favorable reconsideration, withdrawal of the rejections set forth in the above-noted Office Action, and an early Notice of Allowance are requested.

Applicants' undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should be directed to our address given below.

AUTHORIZATION

Applicants believe there is no fee due in connection with this filing. However, to the extent required, the Commissioner is hereby authorized to charge any fees due in connection with this filing to Deposit Account 50-1710 or credit any overpayment to same.

Respectfully submitted,



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EXHIBIT A

**MARKED-UP VERSION OF THE SPECIFICATION
U.S. PATENT APPLICATION NO. 09/826,960**

At page 8, replace lines 3-13 with:

In one aspect, the present invention provides particles having a desired magnetic response. The phrase “magnetic response” refers to attractive or repulsive forces as a result of the application of a magnetic field. The magnetic response can be, for example, migration rate or retention time in response to a magnetic field. “Desired” implies that the amount and type of magnetic material associated with the core particle are chosen by the skilled artisan to provide a core particle having a magnetic response suitable to achieve the skilled artisan’s preferred end result [to achieve a target magnetic response]. The migration rate need not be quantitative (e.g. distance/time), but[by] may be qualitative (e.g., faster or slower than another population of particles). So too, retention time may be quantitative or qualitative. The phrase “population of particles” refers to a set of particles that are similar, for example in magnetic response and other classification parameters (such as fluorescent intensity) where relevant, to the extent they can be identified as belonging to that population.

EXHIBIT B

**MARKED-UP VERSION OF THE CLAIMS
U.S. PATENT APPLICATION NO. 09/826,960**

1. (Once Amended) A particle, comprising:

a core particle; and

at least one substance, associated with said core particle, comprising magnetic material and polymeric material, wherein an[the] amount and type of magnetic material in said[the] substance ranges from greater than 0% to nearly 100% of said[the] substance, and wherein said[the] amount and type of magnetic material [associated with the particle] is chosen to achieve a desired magnetic response from said particle upon exposure to a magnetic field.

4. (Once Amended) A particle according to Claim 1, wherein the at least one substance is a [polymeric magnetic] nanosphere comprising polymeric material and magnetic material.

6. (Once Amended) A particle, comprising:

[at least one magnetic substance in an amount effective for achieving a desired magnetic response; and] a core particle; and

an amount of at least one magnetic substance, associated with said core particle,
wherein said amount of said at least one magnetic substance is effective to achieve a desired magnetic response from said particle upon exposure to a magnetic field.

20. (Once Amended) A set of particles, comprising:

pooled populations of particles comprising at least a first population of particles and another population of particles, wherein[the] particles of each population comprise[comprising] at least one magnetic substance in an amount effective for achieving a desired magnetic response upon exposure to a magnetic field, and wherein said[a] first population of particles is[being] distinguishable from said another population of particles based at least on said desired [the] magnetic response of the particles within said[the] first population upon exposure to a magnetic field.

21. (Once Amended) A method of forming magnetically-responsive particles, comprising:
associating with a particle at least one magnetic substance in an amount effective for achieving a desired magnetic response upon exposure to a magnetic field.

22. (Once Amended) A method according to Claim 21, wherein the at least one magnetic substance is covalently linked to said[a] core particle.

25. (Once Amended) A method of forming a magnetically-responsive population of particles, comprising:

selecting an amount of magnetic substance for achieving a desired magnetic response upon exposure to a magnetic field;

selecting a population of particles wherein particles of said population comprise core particles; and

associating the amount of magnetic substance with said core particles.

EXHIBIT C

**THE CLAIMS WHICH WILL BE PENDING
UPON ENTRY OF THE PRESENT AMENDMENTS
(Filed December 20, 2002)
U.S. PATENT APPLICATION NO. 09/826,960**

1. (Once Amended) A particle, comprising:

a core particle; and

at least one substance, associated with said core particle, comprising magnetic material and polymeric material, wherein an amount and type of magnetic material in said substance ranges from greater than 0% to nearly 100% of said substance, and wherein said amount and type of magnetic material is chosen to achieve a desired magnetic response from said particle upon exposure to a magnetic field.
2. (Once Amended) A particle according to Claim 1, wherein the core particle is a microsphere or bead.
3. A particle according to Claim 2, wherein the microsphere or bead ranges in size from about 1 μ m to about 100 μ m.
4. A particle according to Claim 1, wherein the at least one substance is a nanosphere comprising polymeric material and magnetic material.
5. A particle according to Claim 4, wherein the size of the nanosphere and the amount of the nanosphere is chosen to achieve the desired magnetic response.

6. (Once Amended) A particle, comprising:
 - a core particle; and
 - an amount of at least one magnetic substance, associated with said core particle,wherein said amount of said at least one magnetic substance is effective to achieve a desired magnetic response from said particle upon exposure to a magnetic field.
7. A particle according to Claim 6, further comprising at least one reactant.
8. A particle according to Claim 7, wherein the at least one reactant has a surface-reactive moiety chosen from amines, thiols, carboxylic acids, hydrazines, halides, alcohols, and aldehydes.
9. A particle according to Claim 6, wherein the at least one magnetic substance is chosen from ferromagnetic, paramagnetic and superparamagnetic materials.
10. A particle according to Claim 6, wherein the at least one magnetic substance includes a magnetic component chosen from magnetite, hematite, chromium dioxide, and ferrite alloys.
11. A particle according to Claim 6, wherein the magnetic substance has a magnetic content ranging from greater than 0% to 100%.

12. A particle according to Claim 6, wherein the magnetic substance further comprises polymeric material.
13. A particle according to Claim 12, the magnetic substance comprising a core of 100% magnetic material and a coating comprising polymeric material.
14. A particle according to Claim 6, wherein the at least one magnetic substance is chosen from magnetic nanospheres.
15. A particle according to Claim 14, further comprising non-magnetic nanospheres.
16. A particle according to Claim 15, wherein the core particle is uniformly coated with the at least one magnetic substance.
17. A particle according to Claim 6, wherein the core particle is uniformly coated with the at least one magnetic substance.
18. A particle according to Claim 17, wherein the core particle is completely coated with the at least one magnetic substance.
19. A particle according to Claim 6, further comprising at least one fluorescent tag.
20. (Once Amended) A set of particles, comprising:

pooled populations of particles comprising at least a first population of particles and another population of particles, wherein particles of each population comprise at least one magnetic substance in an amount effective for achieving a desired magnetic response upon exposure to a magnetic field, and wherein said first population of particles is distinguishable from said another population of particles based at least on said desired magnetic response of the particles within said first population upon exposure to a magnetic field.

21. (Once Amended) A method of forming magnetically-responsive particles, comprising:
associating with a particle at least one magnetic substance in an amount effective for achieving a desired magnetic response upon exposure to a magnetic field.

22. (Once Amended) A method according to Claim 21, wherein the at least one magnetic substance is covalently linked to said core particle.

23. A method according to Claim 21, wherein the at least one magnetic substance is chosen from magnetic microspheres.

24. A method according to Claim 23, wherein the size and number of the magnetic microspheres determines the amount effective for achieving a desired magnetic response.

25. (Once Amended) A method of forming a magnetically-responsive population of particles, comprising:

selecting an amount of magnetic substance for achieving a desired magnetic response upon exposure to a magnetic field;

selecting a population of particles wherein particles of said population comprise core particles; and

associating the amount of magnetic substance with said core particles.

26. A method according to claim 25, wherein the magnetic substance is chosen from magnetic nanospheres, and the amount of magnetic substance is selected by choosing the size of the microspheres, the type of magnetic content of the microspheres, the concentration of magnetic content of the magnetic microspheres, and the number of microspheres.

27. A method of forming a pooled set of magnetically-responsive populations of particles, comprising:

combining a population of particles having a desired magnetic response with at least one other population of particles having a different desired magnetic response.

28. A method according to claim 27, wherein the magnetic response relates to the amount of at least one magnetic substance within or associated with core particles in a population.